K012394

AUG 1 5 2001

Oridion

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3.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Product name

Proprietary: Oridion MAC-Line Oral Nasal Cannula sample line
Common: Oral Nasal Gas sampling line for capnograph

Establishment registration number

Establishment registration number: 8044004

Establishment address:

Oridion Medical 1987 Ltd.
Har Hotzvim Science Based Industrial Park
POB 45025
91450 Jerusalem, Israel

Device listing FDA form 2892:

A 733250

Product Classification

The Oridion MAC-Line Oral Nasal Cannula sample line is classified Class II, Product Code 73 CCK.

Intended use:

The intended use of the Oridion MAC-Line Oral Nasal Cannula sample line is to conduct a sample of the patient's breathing from the patient to the gas measurement device for measuring the percentage of CO_2 in the patient's exhalation. The intended use of the modified device, as described in its labeling, has not changed as a result of the modification.

Device description

The common product name for this device is an oral nasal cannula gas sampling line. The gas sampling nasal cannula is used with a capnograph (carbon dioxide analyzer 21CFR 868.1400). There is a sampling cannula at one end of the device for connecting to the patient's nose and mouth and a Male or Female Luer on the other end for connecting to the capnograph. The design and construction of the Oridion MAC-Line Oral Nasal Cannula sample line is identical to the Microstream Nasal Cannula Filterline (K011050) except for the modification which consists of removing the hydrophobic in line filter.

The two connectors are joined by a plastic tube.

One end of the tube is connected to the source of the patient's exhalation (nose and mouth and the other end of the tube is connected to a capnograph. The capnograph has a pump that creates a vacuum which draws a sample of the patient's breathing (exhalation) through the sampling tube into the capnograph for analysis of the CO_2 content of the patient's exhalation.

SUBSTANTIAL EQUIVALENCE:

The Oridion MAC-Line Oral Nasal Cannula sample line is substantial equivalent to the Microstream Oral Nasal Cannula Filterline (K011050) and the Salter Labs Model 4001 Adult, Salter Labs Model 4101 Pediatric (FDA K864199), Oral Nasal Cannula, these devices legally marketed in the USA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 5 2001

Mr. Sanford Brown
Regulatory Affairs Manager
Oridion Medical 1987 Ltd.
P.O. Box 45025
Jerusalem 91450
Israel

Re: K012394
Oridion Mac-Line Oral Nasal Cannula Sample Line
Regulation Number: 868.1400
Regulatory Class: II (two)
Product Code: 73 CCK
Dated: July 23, 2001
Received: July 27, 2001

Dear Mr. Brown:

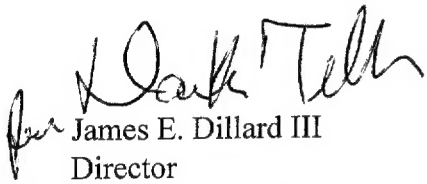
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Oridion

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July 23, 2001

5.0 Indications For Use

510(k) Number (if known): K012394

Device Name:

July 23, 2001

Indications For Use:

The Oridion MAC-Line Oral Nasal Cannula sample line device is used whenever the physician needs to measure the CO_2 in a patient's breathing in a non intubated patient.

The intended use of the Oridion MAC-Line Oral Nasal Cannula sample line is to conduct a sample of the patient's breathing from the patient to the gas measurement device for measuring the percentage of CO_2 in the patient's exhalation. The intended use of the modified device, as described in its labeling, has not changed as a result of the modification.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012394